



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

National Institutes of Health Electronic Application System for Certificates of Confidentiality

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on August 18, 2016 (81 FR 55207-55208) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Ann Hardy, NIH Extramural Human Research Protections Officer and NIH Coordinator, Certificates of Confidentiality, 3701 Rockledge Dr. Rm. 3002, Bethesda, MD 20892, or call non-toll-free number (301) 435-2690 or E-mail your request, including your address to: hardyan@od.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Office of Extramural Research (OER), NIH, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the NIH has submitted to the OMB a request for review and approval of the information collection listed below.

Proposed Collection: Certificate of Confidentiality Electronic Application System, 0925-0689, expiration date 01/31/2017, OER, NIH.

Need and Use of Information Collection: This application system provides one electronic form to be used by all research organizations that wish to request a Certificate of Confidentiality (CoC) from the NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. §241(d)), CoCs are issued by the agencies of Department of Health and Human Services (HHS), including the NIH, to authorize researchers conducting sensitive research to protect the privacy of human research subjects by enabling them to refuse to release names and identifying characteristics of subjects to anyone not connected with the research. At the NIH, the issuance of CoCs has been delegated to the individual NIH Institutes and Centers (ICs). To make the application process consistent across the entire agency, OER launched an electronic application system in 2015 that is used by research organizations that wish to request a CoC from any NIH IC. Having one system for all CoC applications to the NIH is more efficient for both applicants and NIH staff who process these requests. The NIH uses the information in the application to determine eligibility for a CoC and to issue the CoC to the requesting organization. It is anticipated that the NIH ICs will issue approximately 1300 new CoCs each year for eligible research projects.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours estimate is 1,951.

Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (in hours)	Total Annual Burden Hours
CoC Applicants-	455	1	90/60	683

Private				
CoC Applicants- State/local	650	1	90/60	975
CoC Applicants- Small business	130	1	90/60	195
CoC Applicants- Federal	65	1	90/60	98

Dated: October 25, 2016

Lawrence A. Tabak, D.D.S., Ph.D.

Deputy Director

National Institutes of Health

[FR Doc. 2016-26445 Filed: 11/1/2016 8:45 am; Publication Date: 11/2/2016]